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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/672,586	09/26/2003	John D. Puskas	16294-0137 (52433-292707)	8660
7590 10/18/2005 JAMES G. TAUSCHE 5231 POWERS FERRY ROAD ATLANTA, GA 30327			EXAMINER MULLEN, KRISTEN DROESCH	
			ART UNIT	PAPER NUMBER

3766

DATE MAILED: 10/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/672,586

Applicant(s)

PUSKAS, JOHN D.

Examiner

Kristen Mullen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 9/23/05 (RCE).
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 31-60, 131-144, 147-150 and 155-185 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 131-144, 155 and 156 is/are allowed.
- 6) ☒ Claim(s) 31-60, 147-150 and 157-185 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 11/26/04, 3/3/05.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Specification

1. The specification contains a reference to the parent application by its application number.

This application has since been issued. The examiner respectfully requests that the parent application information be updated in the specification along with any other referenced application numbers in the specification that have matured into patents.

2. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following title is suggested: VAGAL STIMULATION VIA JUGULAR VEIN.

Claim Objections

3. Claims 45 and 60 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 149 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 149 recites the limitation "the step of inserting an electrode *into* the neck of said patient" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claim 185 is rejected under 35 U.S.C. 102(e) as being clearly anticipated by Taylor et al. (5,913,876). Taylor shows placing an electrode and actuating the electrode to create an electrical field effective to stimulate the vagus nerve to achieve controlled asystole.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 31-60, 147-150 and 157-184 are rejected under 35 U.S.C. 103(a) as being unpatentable over Taylor et al. (5,913,876) in view of Adams (5,792,187).

With respect to claims 31 and 157, Taylor shows actuating an electrode to create an electrical field effective to stimulate the vagus nerve to achieve controlled asystole. Although Taylor fails to show inserting an electrode into the jugular vein of a patient, attention is directed to Adams who teaches inserting an electrode into the jugular vein of a patient to stimulate the right and left vagal nerves. Adams teaches that the left and right vagus nerves lie closely

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adjacent their respective internal jugular veins through most of the distance of the neck allowing the electrodes to lie at various points along the respective jugular veins (Col. 5, lines 1-5). It would have been obvious to one with ordinary skill in the art at the time the invention was made to modify the method of Taylor to include inserting an electrode into the jugular vein of a patient since Adams teaches that electrodes placed in the jugular vein of a patient can be used to stimulate the vagal nerves and that the jugular vein electrodes can lie at various points along the jugular vein due to the left and right vagus nerves lying closely adjacent their respective internal jugular veins through most of the distance of the neck.

Regarding claims 32, 147 and 158, Adams further shows the step of inserting an electrode into the jugular vein of said patient comprises the step of inserting a first electrode (36) into the jugular vein of said patient; wherein the method comprises the step of inserting a second electrode (38) into the jugular vein of said patient in spaced apart relation to said first electrode; and wherein said step of actuating said electrode to create an electrical field comprises the step of actuating at least one of said first and second electrodes to create an electrical field (Col. 4, line 62-Col. 5, line 5).

With respect to claims 33-35, 148 and 159-161, Although Adams fails to teach inserting a second electrode into a jugular vein of the patient approximately one centimeter from said first electrode and actuating both the first and second electrodes to create an electrical field but rather shows an electrode presumably operating in unipolar mode in each jugular vein, attention is directed to Taylor who teaches that bipolar stimulation is more efficient than unipolar vagal stimulation (Col. 11, lines 9-13) and it is advantageous for the electrodes to be about one centimeter apart for the bipolar stimulation of the vagus nerve (Col. 7, lines 55-63). It would

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have been obvious to one with ordinary skill in the art at the time the invention was made to modify the method of Taylor and Adams to include inserting a second electrode into the jugular vein approximately one centimeter from the first electrode since Taylor teaches that bipolar stimulation is more efficient than unipolar stimulation and that it is advantageous for the electrodes to be about 1 centimeter apart for the bipolar stimulation of the vagus nerve.

With respect to claims 46 and 171, Taylor shows actuating an electrode to create an electrical field effective to stimulate the vagus nerve to achieve controlled asystole. Although Taylor fails to show positioning an electrode on a neck of the patient, attention is directed to Adams who teaches positioning an electrode on a neck of a patient to stimulate the right and left vagal nerves non-invasively (Fig. 2). It would have been obvious to one with ordinary skill in the art at the time the invention was made to modify the method of Taylor to include positioning an electrode on the neck of a patient in order to stimulate the right and left vagal nerves non-invasively rather than via surgical incisions in order to minimize the number of possible complications during a surgical procedure.

Regarding claim 47, 149 and 172, Adams shows the step of positioning an electrode on the neck of said patient comprises the step of positioning a first electrode (66) on the neck of said patient; wherein said method comprises the further step of positioning a second electrode (68) on the neck of said patient in spaced apart relation to said first electrode; and wherein said step of actuating said electrode to create an electrical field comprises the step of actuating at least one of said first and second electrodes to create an electrical field (Col. 5, lines 36-39, lines 51-57).

With respect to claims 48-50, 150 and 172-175, Although Adams fails to teach positioning a second electrode on the neck of the patient one centimeter from said first electrode

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and actuating both the first and second electrodes in a bipolar mode to create an electrical field, but rather shows an electrode presumably operating in unipolar mode at each site on the neck, attention is directed to Taylor who teaches that bipolar stimulation is more efficient than unipolar vagal stimulation (Col. 11, lines 9-13) and it is advantageous for the electrodes to be about one centimeter apart for the bipolar stimulation of the vagus nerve (Col. 7, lines 55-63). It would have been obvious to one with ordinary skill in the art at the time the invention was made to modify the method of Taylor and Adams to include the positioning of a second electrode on the neck of the patient approximately one centimeter from the first electrode since Taylor teaches that bipolar stimulation is more efficient than unipolar stimulation and that it is advantageous for the electrodes to be about 1 centimeter apart for bipolar stimulation of the vagus nerve.

Regarding claims 36-37, 51-52, 162-163 and 176-177, Taylor shows the vagus nerve is stimulated for a period of about five seconds (Col. 5, lines 34-39).

With respect to claims 38-39, 54-55, 164-165 and 178-179, Taylor shows applying an impulse at a frequency of 25 Hertz (Col. 5, lines 34-39).

Regarding claims 42, 57, 168 and 182, Taylor shows applying an impulse having an amplitude of 20 volts.

With respect to claims 44, 59, 170 and 184, Taylor shows the vagus nerve stimulation is performed during off-pump coronary artery bypass.

Regarding claims 40-41, 43, 55-56, 58, 166-167, 169, 180-181 and 183, Taylor and Adams disclose the claimed invention except for applying an electrical impulse at a frequency of forty Hertz, having a duration of 0.4 msec and an amplitude of about two to six volts. It would have been an obvious design choice to one with ordinary skill in the art at the time the invention

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was made to modify the electrical impulse duration as taught by Taylor and Adams with an electrical impulse having a frequency of forty Hertz, having a duration of 0.4 msec and an amplitude or about two to six volts voltage duration of 0.4 msec, since applicant has not disclosed that this particular duration of electrical impulse provides any criticality and /or unexpected results and it appears that the invention would perform equally well with any electrical impulse duration such as the electrical impulse duration taught by Taylor and Adams for stimulating the vagus nerve.

Double Patenting

10. Claims 157-184 are objected to under 37 CFR 1.75 as being substantial duplicates of claims 31-60. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Allowable Subject Matter

11. Claims 131-144, 155-156 are allowed.

Although Taylor shows stimulating electrodes on both the neck and in the jugular vein for stimulating the vagus nerve, it appears that these are separate embodiments shown concurrently in the same figures.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristen Mullen whose telephone number is (571) 272-4944. The examiner can normally be reached on M-F, 10:30 am-6:30 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on (571) 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Kristen Mullen
Patent Examiner
Art Unit 3766

kdm